METHOD, SYSTEM AND COMPUTER PROGRAM PRODUCT FOR PORTABLE, INTERNET-ENABLED, PATIENT MONITORING SYSTEM

ABSTRACT OF THE DISCLOSURE

The present invention describes methods and apparatus useful in remotely modifying medical protocols by subgroups that are defined by specific database characteristics. In addition individual patient protocols may also be remotely modified. The method has application in medical databases containing the data collected by remote device monitoring of outpatients. These outpatients may be managed by one or more medical treatment or clinical research protocols or regimens involving pharmaceutical drugs, physiological data, educational content, and health status assessment or quality of life questionnaires. This method of mass customization of medical protocols, present in a medical database, is useful in efficiently monitoring and managing medical outpatients, through simultaneously instructing selected patient subgroups present in the database to make a change in their respective medical protocols. These changes are to be applied to all members of the selected medical subgroup; and in addition the method provides for specific patient instructions for the individualized components of the medical protocols. By using the mass customization method whereby subgroup selected changes are combined with individualized changes, both population management and individual patient management goals may be realized

The present invention further describes methods and apparatus useful in translating a complex medical treatment plan of a medical outpatient into a sequential series of automated, prompt and record events presented over time. In addition, individual patient medical treatment plans may be remotely created, modified, or viewed depending upon role-based assignments that permit different levels of access to and modification of the patient's time-and-event-driven medical treatment plan, depending upon the assigned role of the caregiver in the patient's treatment. The method has application in creating and linking medical databases containing data points that define the outpatient's medical treatment plan or protocol, with devices that can prompt the outpatient to carry out the sequential steps of a medical treatment plan, in

proximity to the database, or while mobile at remote locations from the database.

This method facilitates converting a complex medical treatment plan into a series of simple steps presented by the remote prompting and monitoring device, to assist patients and their caregivers in proper health management. By using the real-time, time-and-event-driven method, individual patient management goals and improved patient treatment outcomes may be realized by outpatients with chronic and complex conditions.

The present invention further describes methods and apparatus useful in translating real-time recorded information from medical outpatients into analyzed and formatted information, and recommended treatment interventions, that are broadcast in real-time to the caregivers or family members of these outpatients. The recorded information may include medication compliance, health status, quality-of-life, physiologic, laboratory, or other medical data that is captured in real-time from medical outpatients, and stored in a database that hosts individualized and population-based complex medical treatment plans and/or medical protocols. The database provides for the creation of patient treatment plans by a mass-customization method, whereby individual patients can be assigned treatment unique to their clinical situation, and treatment based upon a group or population to which they belong. The database provides for: analysis of the real-time outpatient data captured from the patients; bio-statistical analysis and stratification of patients based upon their respective risks of developing worsening clinical outcomes, and increased medical costs; pattern recognition analysis of medical data to determine new correlation of data elements; and broadcast of real-time information to the respective caregivers and family members of the patients. The real-time information broadcast to the caregivers can include raw data and/or analyzed and formatted data recorded from the patients; patient deviations from acceptable population-based and/or individual patient standards; predictions of the clinical and economic risks associated with the respective patients' conditions; new patterns of correlation among medical and/or non-medical data elements; and guidelines for medical interventions. Medical decision support software may be used to analyze and correlate the

data captured from the patient, and generate recommendations for treatment interventions. After a review of the analyzed data, the caregiver or family member can then update the patient's medical treatment plan with new instructions, or communicate new instructions directly to the patient. When patients and their family members and caregivers carry wireless devices that are linked with the database via the Internet, the entire information system operates in real-time. By using this real-time analysis and triage method, individual patient management goals, improved patient treatment outcomes, real-time outcomes research, and reduced medical costs may be realized by outpatients with chronic and complex conditions.

The present invention further describes methods and apparatus useful in translating a complex medical treatment plan of a medical outpatient into a sequential series of automated, prompt and record events presented over time; to two or more medical monitors used by a single patient. The medical monitors are linked to a database that updates and synchronizes the information presented to all of the monitors, and captures information from all of the monitors. Individual patient medical treatment plans may be remotely created, modified, or viewed in the database; and in turn are transformed by business logic rules and a communications system into prompted and recorded events that are delivered to the patient by two or more remote monitors. In the alternative, the patient selects a specific monitor that he or she will use at a specific time, and the database senses the monitor in active use by the patient and communicates with it directly. The method has application in creating and linking medical databases containing data points that define the outpatient's medical treatment plan or protocol, with multiple different devices with different characteristics, that can prompt the outpatient to carry out the sequential steps of a medical treatment plan, and record the patient's responses. The patient can self-select the monitor that he or she will be using for a particular lifestyle preference at a particular time. The monitored outpatient may be managed by one or more medical treatment or clinical research protocols or plans that involve; pharmaceutical drugs, physiologic data, treatment instructions, medical educational content, medication compliance assessment, and health status or quality of life assessment. Each of these protocols or plans is first translated into a set of data points stored in a

medical database and configured as a patient medical file. The data points are then translated into a sequence of time-and-event-driven, graphic and/or auditory, real-time communications presented to the patient or caregiver via two or more different remote devices that are linked to the database. Regardless of which device is used, in the event of graphic communications, the formatting remains consistently presented to each one of the multiple device displays. The patient then interacts with two or more remote devices that record these interactions in real-time, and communicate the recorded data to the database in real-time or via store-and-forward means. This method facilitates converting a complex medical treatment plan into a series of simple steps presented by the remote prompting and recording facilitated by the monitoring devices, to assist patients and their caregivers in proper health management. By using the method of multiple medical monitoring devices synchronized by a central database, the patient will be able to properly carry out a complex medical treatment plan or clinical drug trial protocol involving the use of two or more monitoring devices. The patient will have greater freedom of choice regarding which device is used at a particular time, enabling better integration of the entire monitoring system into the patient's lifestyle, in turn resulting in better compliance by the patient with the medical treatment plan.

The present invention further describes methods and apparatus useful in analyzing the dose-specific effects of pharmaceutical agents upon the patient or populations of patients, based upon statistical analysis and data mining of data contained in a medical database. The medical database may contain the following real-time data captured from patients: medication compliance for one or more medications taken by the patient, patient answers to health status and quality-of-life questionnaires, patient physiologic data, and patient laboratory data. This data may also be combined with other database data such as genomic, proteomic, phenotypic, economic, and other healthcare related data, for further data analysis. The statistical analysis and data mining of the data includes the method of correlating patient medication dosing patterns of one or more drugs ingested by the patient, with various other measures of clinical and economic outcomes of the patients. The method is based in translating a complex medical treatment plan of a medical outpatient

into a sequential series of automated, prompt and record events presented over time; to two or more medical monitors used by a single patient. The medical monitors capture data on medication compliance, health status, quality-of-life, physiologic status (e.g. blood pressure, EKG, pO2, pulse rate, weight, pulmonary function, etc.), and various measures of blood, serum, urine, and other laboratory tests. The medical monitors are linked to a database that updates and synchronizes the information presented to all of the monitors, and captures information from all of the monitors. Individual patient medical treatment plans may be remotely created, modified, or viewed in the database; and in turn are transformed by business logic rules and a communications system into prompted and recorded events that are delivered to the patient by the remote monitors. The patient monitoring data may then be combined with genomic, proteomic, and phsyiologic data for analysis and data mining purposes. In addition, the method provides for each device to record whether the patient is following the treatment plan; and to upload that recorded data to the database; which provides for monitoring the progress of treatment as the individual patient uses multiple monitoring devices. The method has application in clinical drug trials and outcomes research protocols, which are designed to determine the therapeutic effects, side effects, adverse drug events, and costs of new pharmaceutical agents, and agents that are already on the market. It also has applications in targeting specific drugs at specific doses for specific patient populations, to optimize patient outcomes and minimize side effects, adverse drug events, and costs.

The present invention further describes methods and apparatus useful in remotely modifying a medical treatment protocol, to improve a patient's adherence to his or her medication regimen and medical treatment protocol through musical alarms. Individual patient medical treatment protocols may be remotely created and modified, and may include specific musical compositions that are audibly presented to the patient at pre-selected times over one or more medical monitoring devices used by the patient. An audible musical alarm is presented to the patient in association with a prompted event, as part of an information system designed to prompt the patient to follow particular elements of the medical treatment plan. An audible musical alarm is presented with each of the following events: "Alarm" Event, which is the

sound made when there is an event prompted for the taking of medication, answering a questionnaire, or another instruction, such as the use of a physiological monitoring device; "KeyClick" Event, which is the sound made when a button is pressed on a medical monitoring device at an acceptable time; "BadKeyClick" Event which is the sound made when a button is pressed on the medical monitoring device at an unscheduled time; "DrawerOpenGood" Event, which is the sound made when a medication drawer is opened at a scheduled time; "DrawerOpenBad" Event, which is the sound made when a medication drawer is opened at an unscheduled time; "DrawerClose" Event, which is the sound made whenever a medication drawer is closed; and other event-associated sounds related to prompting the patient to follow his or her medical treatment plan. Each musical alarm can be self-selected by the patient from a menu of possible selections, based upon the musical alarm that is most desired by, and most motivating for the patient to follow the medical treatment plan. By using the creation and self-selection of musical alarms method, patient adherence to medication regimens and medical treatment plans will be enhanced, and individual patient management goals may be better realized.

The present invention describes methods and apparatus useful in analyzing the effects of streaming video and pictorial presentations upon the patient or populations of patients, and upon the prescribing physicians; based upon statistical analysis and data mining of data contained in a medical database, physician prescribing patterns, and pharmaceutical sales data. The medical database may contain the following real-time data captured from patients: medication compliance for one or more medications taken by the patient, patient answers to health status and quality-of-life questionnaires, patient physiologic data, and patient laboratory data. This data may also be combined with other database data such as physician prescribing patterns, medication sales, genomic, proteomic, phenotypic, economic, and other healthcare related data, for further data analysis. The statistical analysis and data mining includes the method of correlating one or more streaming video presentations and/or audiovisual and/or visually-presented advertisements independently presented to patients and physicians with the following patient-related data; medication dosing patterns of one or more ingested drugs, various

other measures of clinical and economic outcomes, prescribing patterns of the treating physicians, and sales of the medications. The method may based in translating a complex medical treatment plan of a medical outpatient into a sequential series of automated, prompt and record events presented over time; to medical monitors or other data capture devices used by patients. The method has application in providing a much more targeted approach to direct-to-consumer and direct-to-physician advertising campaigns of pharmaceutical companies, which are designed to maximize the sales of specific medications.

The present invention further describes methods and apparatus useful in enhancing pharmaceutical advertisements, drug positioning and branding, and drug package inserts based upon statistical analysis and data mining of data contained in a medical database. The medical database may contain the following real-time data captured from patients: medication compliance for one or more medications taken by the patient, patient answers to health status and quality-of-life questionnaires, side effects ratings of the medications, adverse drug events, drug interactions, patient physiologic data, and patient laboratory data. This data may also be combined with other database data such as genomic, proteomic, phenotypic, economic, drug interaction, and other healthcare related data, for further data analysis. The statistical analysis and data mining includes the method of correlating the following patient-related data: medication dosing patterns of one or more ingested drugs, and various other measures of clinical and economic outcomes, and then using this information to more accurately differentiate the advantages of a particular pharmaceutical agent over its competitors, and more accurately position and brand the pharmaceutical agent. By creating medical databases containing data points that define the outpatient's medical treatment plan or protocol, and then presenting this information over real-time patient monitoring devices or other data capture devices that can record the patient's responses; the data thereby presented and derived can be analyzed and mined; and be combined with physician prescribing, drug sales, genetic, proteomic, and phenotypic data for further analysis; to determine the correlation between drug sales, medication compliance, patient outcomes, and costs of treatment. The method has application in providing more scientifically valid information about medication effects for use in advertising campaigns of pharmaceutical

companies, which are designed to maximize the sales of specific medications, in an increasingly competitive marketplace. In addition, the method has application in providing more accurate information for drug package inserts mandated by the Food and Drug Administration for all prescription medications.

The present invention further describes methods and apparatus useful in managing financial transactions and customer relations related to various online devices used by individuals; by synchronizing and automating the monitoring, data recording, accounting, calculating of sales commissions, calculation of license fees and royalties, vendor invoicing, customer relations management and customer feedback, rank-ordering and triaging of critical data, and billing and collecting functions necessary for the commercial use of these online devices by individuals. The devices may include any medical devices, medical monitors, telemedicine devices, and other types of online monitors, information devices, and controllers. The online devices are linked to a database that updates and synchronizes the financial transaction information permitting device use with the information captured from all of the devices. The linkage between the online devices and the database is via communications means that may include traditional modem, wireless modem, other wireless transmissions, cable modem, fiber-optic cable modem, laser, other light beam, or other means. Individual, group or site-based user transaction arrangements, that define the terms and conditions of device use, may be remotely or directly created, modified, or viewed in the database. The transaction terms and conditions are transformed by business logic rules and a communications system into a series of services provided to the device users via the devices and the database over a finite time period. The method and apparatus may also provide for customer relations management and customer response information, outbound messaging based upon the criticality of received data, the calculation of the sales commissions for the salespeople; license fees and royalties; accounting reports; user billing via debit card, credit card, mailed invoices, or other means of electronic commerce; and account collection activities. Inputs into the transaction-based monitoring and accounting system may include financial transaction terms, lease or rental terms that define the "purchased window" of services, approved online days

by device, billing status questions, clinical/healthcare professional locator/medical test results questions, commission structure for salespeople, data from monitoring devices, record of customer payments, customer satisfaction and wish-list data, record of other database services purchased by the device user, instant messages targeted to peer group members, and other data. The transaction-based business logic rules provide for report generation algorithms, triage of critical data to selected individuals, a record of payment versus transaction terms, financial calculations, and a determination of service continuation versus service interruption. The outputs from the database system include payroll, sales bonus calculations, license and royalty calculations, device activation and deactivation data, device malfunction data, customer response data, number of devices in use by site and time period, device user charges, user charges for other database services, charges by site for group users, days of online use by individuals, payment transfers into a lock-box, warning messages to the users or site if payments are in arrears, and termination of service if payment is not forthcoming, and outbound messages based upon the triage functions. The method has application in customer response management and in converting the financial terms and conditions for outpatient monitoring services provided by an applications services provider company ("ASP") into the approved delivery of patient monitoring and other consumer services. By using the method of transaction-based monitoring, customer relations management, and accounting, application service provider companies ("ASPs") are better able to commercialize their information system operations, by linking the complex financial transactions for service delivery to actual device usage patterns, sales commissions, payroll, accounting reports, license and royalty fees, and a determination of continuation versus discontinuation of service, and warning messages based upon the payment status of each device-related transaction. The method also provides for real-time solicitation of customer responses regarding the quality of services provided, and a wish-list of desired new services.

The present invention further describes methods, apparatus, and operating system useful in rapidly linking medical outpatients and their caregivers to medical information that is both specifically relevant to the patients' medical conditions, and scientifically validated. Dynamically

generated interactive screens, and/or interactive voice prompts are presented to patients and caregivers to provide hyperlinks to medical information content that is specifically relevant to optimizing the personal health condition, and medical treatment plans of the patients. The screens provide for icons that, when selected, link the patient and/or caregiver to targeted database information to optimize the patients' and caregivers' knowledge base, and improve the health and treatment of the patient. Voice prompts may also be used to access the database information. The dynamically generated screens may be remotely created, modified, or viewed through role-based assignments granted to the patient, their caregivers, their adult children, and/or the medical professionals responsible for the patients' care. In one embodiment of the invention, the icons are arrayed on the screen of a device, and symbolize medications, side effects, adverse drug events, illnesses or diagnoses, medical treatments, decision support algorithms, evidence-based medical treatment recommendations, health promotion activities, patient queries, physical characteristics, physiologic tests, laboratory tests, protein chip data, genomic data, radiographic tests, other biologic measures of the patient, and any other icons that symbolize a link to medical information pertinent to the patients' healthcare, treatment and condition. These icons may be pictorial or symbolic representations, and/or key words. The same method of linkage can be provided by pre-selected and programmed voice prompts that are entered into the devices. The information provided through the associated links facilitates the support of a patient's complex medical treatment plan by providing the patient and caregiver the opportunity to rapidly locate in real-time patient-specific and population-specific knowledge, to assist patients and their caregivers in optimizing health management. By using the dynamic interactive screen and voice-prompt method, individual patient management goals and improved patient treatment outcomes may be realized by outpatients with chronic and complex conditions, and the caregivers who treat them.

The present invention further describes methods and apparatus useful in remotely modifying the functional attributes of information devices used by subgroups that are defined by specific database characteristics. It is well known that different subgroups have different device use preferences, desires for information content and data analysis, user abilities, degrees of technologic

and intellectual sophistication, cognitive abilities or impairments, and price-point sensitivities. As well, various regulatory agencies may regulate the use of these devices based upon their being dedicated purpose vs. general purpose devices (e.g. the FDA prefers dedicated information devices in clinical trials that serve one and only one function, that of data capture for the trial). The functional attributes of the remote information devices may assist the subgroups in efficiently managing various activities of daily life, which may include correctly adhering to medical treatment plans or protocols; improving their personal health and wellness promotion activities; better managing their workplace tasks for specific vertical industries; and other activities that are process-driven and information-based. The invention provides for a series of remote devices linked to one or more servers via the Internet, an intranet, or other means of connectivity between client and server. The connectivity may be established via hard wire modem, wireless, light beam, fiber-optic cable, or other means. The invention provides for remotely creating a continuum of device features and functionality that is made available to the user of the device on a subgroup-specific basis; ranging from thin-client devices that host no software applications, and run entirely from server-based software applications; to PC-like devices that host many software applications that run independently of the server, whether the devices are connected to the server or not. Software applications may be remotely downloaded to the client device from the server based upon database characteristics of the device users (e.g. via downloadable Java applets); or the applications may be remotely accessed and used via an ASP service model. In the latter case, the software applications are hosted on the remote server, and are installed, maintained and enhanced by a third party. The method has application in many fields of life, for example the medical management of subgroups of outpatients. These outpatients may be managed by one or more medical treatment or clinical research protocols or regimens involving pharmaceutical drugs, physiological data, educational content, and health status assessment or quality of life questionnaires. This method would result in more targeted and personalized support of the patient, more flexibility in delivering information to the patient and caregiver, more flexibility in the pricing and costs of such services, and more effective healthcare delivery.

The present invention further describes methods, apparatus, and operating system useful in rapidly linking medical databases to improve risk management activities and interventions for outpatients; for better providing pharmacy benefits management (PBM) activities to improve patient outcomes and reduce health costs; for "just-in-time" inventory management of pharmaceutical agents stored in pharmacies; and for better control over the timing of manufacture of pharmaceutical agents to reduce the carrying cost and shelf life of the agents. Through this invention, the entire supply chain related to pharmaceutical products manufacturing, distribution, sales, payment mechanisms, and patient consumption may be optimally managed. Real-time data regarding medication use of outpatients is gathered from devices used by the patients and/or their caregivers, and may be used alone or in combination with medication consumption data captured at the individual pharmacy level, corporate level in the case of chain drug stores, national level in the case of Medicare and/or Medicaid patient drug consumption and reimbursement, and international level in the case of marketing and sales data captured by a pharmaceutical manufacturer. The patient consumption data is transmitted from the individual devices used by the patients to one or more databases that are used to track the pharmaceutical consumption of the patients. The goal is to collect and use the patient medication consumption data to reduce costs to the healthcare system; improve the efficiency and profitability of the patient risk management and disease management companies, pharmacies, PBMs, pharmaceutical manufacturers; and improve clinical outcomes. The patient medication use and consumption data may be captured in real-time, and transmitted to the databases in real-time, using personal computers (PCs), personal digital assistants (PDAs) such as the Palm Pilot or Windows CE devices, wireless information devices (WIDs), cellular telephones, interactive televisions, a proprietary device known as the Med-eMonitor, any other devices that provide a means of capturing this information with links to information contained in one or more databases. The method has application in linking pharmaceutical supply chain companies to databases containing pharmaceutical use information, to better manage supply chain commercial and manufacturing activities.